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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) <div style="text-align: center;">101672.0019P</div>
	Application Number <div style="text-align: center;">10/803,512</div>	Filed <div style="text-align: center;">March 18, 2004</div>
	First Named Inventor <div style="text-align: center;">Guy Rome</div>	
	Art Unit <div style="text-align: center;">3763</div>	Examiner <div style="text-align: center;">Q. H. Vu</div>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"><div style="width: 60%;"><p><input type="checkbox"/> applicant /inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,218</u></p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p></div><div style="width: 35%; text-align: center;"><p>_____ /Todd W. Wight/ Signature</p><p>_____ Todd W. Wight Typed or printed name</p><p>_____ (714) 641-5100 Telephone number</p><p>_____ December 21, 2010 Date</p></div></div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>		
<div style="display: flex; align-items: center;"><input type="checkbox"/> *Total of <u>1</u> forms are submitted.</div>		

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: December 21, 2010

Electronic Signature for Kari Lynn Barnes: /Kari Lynn Barnes/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Guy Rome

Application No.: 10/803,512

Confirmation No.: 5437

Filed: March 18, 2004

Art Unit: 3763

For: MULTIFUNCTION ADAPTOR FOR AN
OPEN-ENDED CATHETER

Examiner: Q. H. Vu

ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully submits the following arguments in support of the Pre-Appeal Brief Request for Review filed concurrently herewith.

In a Final Office Action, mailed September 28, 2010 (hereinafter, "Office Action"), claims 30-33, 40-41, and 44-46 were rejected under 35 U.S.C. § 103(a) as obvious over US Pub. No. 2004/0193119 to Canaud et al. (hereinafter, "Canaud"); claim 47 was rejected under 35 U.S.C. § 103(a) as obvious over Canaud in view of USPN 6,921,396 to Wilson et al. (hereinafter, "Wilson"); claims 30, 40, and 42-47 were rejected under 35 U.S.C. § 103(a) as obvious over Wilson in view of either USPN 4,502,502 to Krug (hereinafter, "Krug") or USPN 4,535,818 to Duncan et al. (hereinafter, "Duncan"); claim 30 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The drawings were also objected to under 37 CFR § 1.83(a) for failing to show recited features within the elected figures.

Applicant respectfully requests the Panel to review the rejection of independent claim 30 as obvious over Wilson in view of either Krug or Duncon, because the proposed combination does not disclose the valve “having a closed proximal end with a slit and an open distal end.” The Panel is also requested to review of the rejection of dependent claims 33 and 41 as obvious over Canaud. The Panel is further requested to review the outstanding objections to the drawings and the rejection of independent claim 30 as indefinite.

Applicants first submit that the rejection of independent claim 30 as obvious over Wilson in view of Krug or Duncon is misplaced at least because the proposed combination discloses the exact opposite configuration as claimed. Wilson shows and describes a catheter assembly without the claimed built-in valve. The valve is assertedly provided by either Krug or Duncan. However, the Krug and Duncan valves are duckbill valves, or similar variations, with a closed distal end and open proximal end. The configuration cannot be turned without preventing flow through the catheter, thus rendering the Wilson device unsuitable for its intended purpose.

Wilson shows and describes a multi-lumen catheter 10 with a multi-lumen catheter tube 16, a flush tube portion 14, and a connector 12. (Wilson, col. 7:29-31.) “The connector 12 and flush tube portion 14 permit the simultaneous flushing of the multiple lumens 30 of the catheter tube 16 with a flushing liquid 62.” (Wilson, col. 8:61-63.) “Flushing liquid 62, such as a saline solution, can be injected through the cavity 22 of the connector 12, through the single lumen 28 of the flush tube portion 14, and into each of the lumens 30 of the catheter tube 16. In this way, each of the plurality of catheter lumens 30 need not be separately flushed in a sequential manner, thereby saving both time and effort during the catheterization process.” (Wilson, col. 8:66-9:6.)

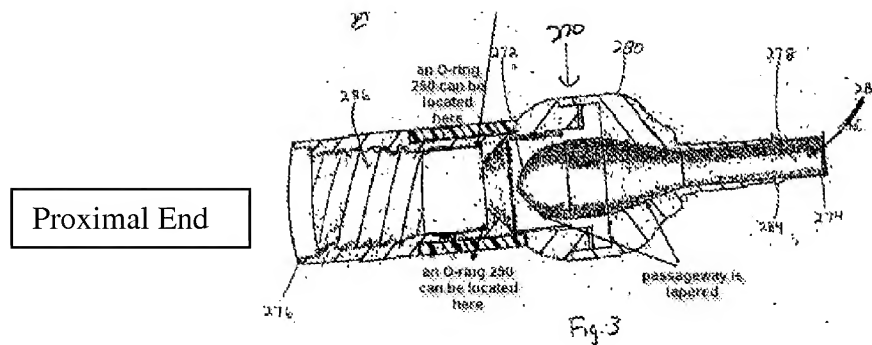
Krug shows and describes a “unidirectional flow regulator or valve 18 [] axially disposed in the body 12 along the length thereof. Such unidirectional valve 18 is well known and recognized in the art sometimes being referred to as a ‘duckbill’ valve.” (Krug, col. 2:31-35.) As seen by arrows of FIG. 2, the closed end of the duckbill valve is on the downstream end of the valve. The valve remains closed, preventing fluid flow when fluid passes in the opposite direction, against the valve.

Duncan similarly shows and describes a valve with “a flow path for permitting relatively free flow in the flow path in a first direction and for preventing flow in the path in a second, opposite direction.” (Duncan, col. 2:52-54.) The valve is configured “so that flow in the first direction is from the first port, through the open end, through the normally closed end, and to the second port.” (Duncan, col. 3:2-4.)

As shown and described, in order to retain the proper functioning of the Wilson connector, the valves of Krug and Duncan would have to be positioned so that the closed end of the duckbill is towards the connected catheter. In this manner, fluid can be inserted from the open end through the normally closed end and then through the catheter as described by the cited references. As claimed, the connector distal end is the end attached to a proximal end of the catheter. Thus, the claimed closed proximal end of the valve is the end away from the catheter. In view of this orientation, the proposed combination results in the exact opposite configuration of the claimed invention. Instead of a closed proximal end, the resulting valve connector has a closed distal end directed toward the connected catheter. The configuration cannot be switched to meet the recitation of the present claims without destroying the purpose of the Wilson connector and rendering it inoperable.

The rejection of dependent claims 33 and 41 as obvious over Canaud is also misplaced because the cited reference does not show the claimed features, and the rationale does not support a *prima facie* case of obviousness.

Dependent claim 33 recites “a wall defining the proximal portion of the passageway proximal of the O-ring is tapered.” As recited by independent claim 30, the distal end is attached to the catheter, and thus the proximal end is identified below with respect to annotated Canaud FIG. 3. As seen in the below annotated Canaud FIG. 3 provided by the Office, the indicated tapered portion is distal to the asserted O-ring position, in contradiction to the present claims.



With respect to dependent claim 41, the Office states that the recitation of “configured to/adapted to/capable of” performing a function does not constitute a limitation in any patentable sense. The Office then states that instead of a threaded connection, other ways in the art are used to engage between two elements, i.e. the syringe adaptor and connector, such as by friction fit. Finally, the Office asserts that a distal end of syringe adaptor either sliding over or into the proximal end of the connector is considered a rearrangement of parts or constructing a structure in various elements, which involves only routine skill in the art. Applicant respectfully disagrees, and submits such conclusory statements without verification cannot support a *prima facie* case of obviousness. The Office fails to show the claimed configuration of a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing. Therefore, such a modification to the Canaud port is not merely a rearrangement of parts or structuring into multiple elements, as asserted by the Office to support a *prima facie* case of obviousness, but instead is a feature not shown or described by the cited combination of references.

The drawings stand objected to for failing to show the recitations of claims 30 and 33 including “a distal end of connector attached to a proximal end of catheter,” “an engagement feature,” and “the engagement feature comprises an O-ring, and where a wall defining the proximal portion of the passageway proximal of the O-ring is tapered.” Applicant respectfully directs the panel to the drawing and specification amendments, as submitted September 29, 2008, including new Figure 7D with catheter 20, O-ring 510, and tapered wall 512.

The Examiner has rejected independent claim 30 as indefinite since it is assertedly unclear which element Applicant considers an engagement feature. Applicant respectfully submits that the language is sufficiently clear and precise to alert a person of ordinary skill in the art of its scope. (MPEP § 2173.02.) Reference to a particular element is not required. Accordingly, such a rejection is improper.

In conclusion, Applicant respectfully requests the panel to review the selected rejections to determine the applicability to the present claims. Specifically, Applicant respectfully submits that the combination of Wilson in view of either Krug or Duncan fails to show or describe the claimed valve, and the claimed configuration is not obvious over the cited references; Canaud fails to show or describe the features of dependent claim 33; and the rejection of dependent claim 41 is not supported by the Office's conclusory statements. Applicant also respectfully requests the withdrawal of the drawing objections and the rejection of independent claim 30 as indefinite.

Due to space restrictions, Applicant does not address with specificity the rejection of dependent claims 40, and 42-47 as obvious over Wilson in view of either Krug or Duncan, or the other rejections within the Office Action. However, since these claims depend from independent claim 30, which is not obvious over the cited references of Wilson, Krug or Duncan in view of the above, these claims are also not obvious and may include additional recitations not shown or described by the cited references. Accordingly, Applicant requests the withdrawal of the rejection of the pending claims as obvious over Wilson.

Dated: December 21, 2010

Respectfully submitted,

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